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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/857,719	12/03/2001	Ryuichi Morishita	6235-59216	9622

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EXAMINER	
LI, QIAN JANICE	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 07/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/857,719	MORISHITA ET AL.	
	Examiner	Art Unit	
	Q. Janice Li	1632	

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 June 2004* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11,14,16,33 and 36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11,14,16,33 and 36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *03 December 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/1/04 has been entered.

The amendment and response filed on 6/1/04 have been entered. Claims 12, 18, and 37-41 have been canceled. Claims 11, 14, 16, 33, and 36 have been amended, are pending in the application and under current examination.

Unless otherwise indicated, previous rejections that have been rendered moot in view of the amendment to pending claims will not be reiterated. The arguments in 6/1/04 response would be addressed to the extent that they apply to current rejection.

Claim Objections

Applicant is advised that should claim 11 be found allowable, claims 16 and 33 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing

one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 11, 14, 16, 33, and 36 stand rejected or newly rejected under 35 U.S.C. 112, first paragraph for reasons of record and following.

As an initial matter, the response fails to address the issue raised in page 3 of the Office action mailed 12/13/03 concerning claim 36. Claim 36 reads on treating any disorder by directly administering into an affected tissue a nucleic acid molecule HVJ-HGF via echocardiography. However, since the echocardiography is an ultrasonic aid for observing the structure and motions of the heart, it is unclear and the specification fails to teach how such tool could be used for direct administration to any affected tissue in the body beyond the heart. The specification as originally filed only provides delivering a nucleic acid to heart tissue under echo guidance, thus, it fails to provide an enabling disclosure to support the full scope of the claim.

These claims recite "the nucleic acid molecule comprising a Sendai virus HVJ liposome". However, since the nucleic acid is surrounded by the liposome and sendai viral proteins, the nucleic acid could not have comprised the HVJ-liposome (e.g. see fig. 1 of *Kaneda et al*, Mol. Med Today 1999;5:298-303). Moreover, liposomes are known to

facilitate the delivery of a naked nucleic acid such as a plasmid vector, the prior art of record (e.g. *Kaneda et al*) and the specification teach using HVJ-liposome for delivering a plasmid DNA, yet instant claims encompass delivering any type of nucleic acid, such as a virus. Neither the art of the record, nor the specification teaches that the HVJ-liposome could promote the delivery of a viral vector expressing viral proteins other than the sendai viral HN and F proteins. Accordingly, the disclosure fails to provide an enabling disclosure to support the full scope of the claims, it would have required undue experimentation for one skilled in the art to make and/or use the claimed invention.

Claim 36 is newly rejected under 35U.S.C. 112 first paragraph, because the specification as originally filed does not describe the invention as now claimed. The original disclosure fails to specify treating *any disorder* via direct introduction of HGF-Sendai HVJ-liposome into *any tissue* as now claimed. The subject matter is now considered to be new matter.

Claim 36 was submitted on 6/17/03, long after the effective filing date. The claim language is confusing because it reads on delivery a nucleic acid to any tissue using an echocardiography. Since according to the common sense, the echo would only help gene delivery to cardiac tissue, the Examiner rejected the claim for lack of enablement for delivery a nucleic acid to any tissue via echo (page 3 of the Office action mailed 12/18/03).

However, in view of the arguments presented in the first paragraph of page 6 (Remark submitted 6/1/04), it becomes clear that applicants intend to claim treating any

disorder that would benefit from increased angiogenesis. Upon further review of the specification, it is determined that the amendment introduced new matter to the disclosure because the specification as originally filed only discloses using echo for gene delivery to *cardiac tissue* for the treatment of myocardiac disorders. Thus, the amendment is a departure from or an addition to the disclosure of the application as filed, accordingly, it introduces new matter into the disclosure.

MPEP 2163.02 teaches that "WHENEVER THE ISSUE ARISES, THE FUNDAMENTAL FACTUAL INQUIRY IS WHETHER A CLAIM DEFINES AN INVENTION THAT IS CLEARLY CONVEYED TO THOSE SKILLED IN THE ART AT THE TIME THE APPLICATION WAS FILED...IF A CLAIM IS AMENDED TO INCLUDE SUBJECT MATTER, LIMITATIONS, OR TERMINOLOGY NOT PRESENT IN THE APPLICATION AS FILED, INVOLVING A DEPARTURE FROM, ADDITION TO, OR DELETION FROM THE DISCLOSURE OF THE APPLICATION AS FILED, THE EXAMINER SHOULD CONCLUDE THAT THE CLAIMED SUBJECT MATTER IS NOT DESCRIBED IN THAT APPLICATION. Applicants are invited to particularly point out where in the specification the support for the full scope of claim 36 could be found.

For reasons set forth above, the amendment filed 6/17/03 and 6/1/04 is objected to under 35 U.S.C. §132 because it introduces new matter into the disclosure. 35 U.S.C. §132 states that no amendment shall introduce new matter into the disclosure of the invention. Applicant is required to cancel the new matter in the reply to this Office Action.

For the interest of a compact prosecution, claim 36 would be examined to the extent that it is drawn to directly delivering a nucleic acid into an affected cardiac tissue under the guidance of echocardiography.

To the extent that the claimed methods are not described in the instant disclosure, claim 36 is also rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, since a disclosure cannot teach one to make or use something that has not been described.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 16 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 16 is vague and indefinite because it is incomplete concerning whether the goal of the method is resolved that would relate back to the preamble.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 11, 14, 16, 33, and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over *WO 97/07824, Esakof et al* (Hum Gene Ther 1999 Sept;10:2307-14) and *Maurice et al* (J Clin Invest 1999;104:21-9), further in view of *Stevens et al* (US 5,916,193).

In the 6/1/04 response, Applicants first argue that none of the cited prior art of record discloses or suggests the use of a Sendai virus HVJ-liposome and HGF to treat myocardiopathy or cardiac muscle disorder. This is in error. As indicated in the Office action mailed 2/12/03 and reiterates here, W0 97/07824 discloses a pharmaceutical composition comprising HGF (2nd paragraph, page 9), which could be packaged in HVJ-liposome (e.g. page 11, line 2). *WO 97/07824* also lists the type of myocardiopathy that could be treated with the HGF (2nd paragraph, page 6), and teaches a method comprising administering the HGF-HVJ-liposome intramuscularly to the heart of a subject (example 8), wherein the HGF-HVJ-liposome could be delivered directly to the cardiac muscle (page 22, lines 18-24).

As discussed in detail in the previous Office action, the combined teachings of *WO 97/07824, Esakof et al, Maurice et al* and *Stevens et al* teach delivering a plasmid nucleic acid encoding a HGF in the form of HVJ-liposome to myocardial tissue through a catheter guided by the transesophageal echocardiography during the open-heart procedure, and using a catheter without thoracotomy.

Concerning claim 36, as indicated in § 112, 1st paragraph, it contains new matter, thus, the claim was only examined to the extend that it is drawn to direct nucleic acid delivery to cardiac tissues, thus the rejection properly applies to claim 36.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the methods taught by *WO 97/07824, Esakof et al*, and *Maurice et al* by adopting the catheter system taught by *Stevens et al* in the nucleic acid cardiac delivery procedure with a reasonable expectation of success. The ordinary skilled artisan would have been motivated to modify the method because it provides a safe and cost-effective means for transgene delivery. Thus, the claimed invention as a whole was *prima facie* obvious in the absence of evidence to the contrary.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Q. Janice Li** whose telephone number is 571-272-0730. The examiner can normally be reached on 9:30 am - 7 p.m., Monday through Friday, except every other Wednesday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Amy Nelson** can be reached on 571-272-0804. The fax numbers for the organization where this application or proceeding is assigned are **703-872-9306**.

Any inquiry of formal matters can be directed to the patent analyst, **Dianiece Jacobs**, whose telephone number is (571) 272-0532.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

JANICE LI
PATENT EXAMINER

Q. Janice Li
Patent Examiner
Art Unit 1632

QJL
July 19, 2004